JUL 9 2002

510(k) Summary of Safety and Effectiveness

Contact	American Optisurgical Inc. 25501 Arctic Ocean Lake Forest, CA 92630 949 580 1266 Nanette Canepa Director, Regulatory Affairs July 3, 2002 510(k): K020527
Name of Device, Common Name and Classification	Name of Device: Horizon Phacoemulsification System Common Name: Phacofragmentation or Phacoemulsification System Classification Name: As per 21 CFR 886.4670, the product nomenclature is Phacofragmentation System.
Predicate Devices	P4000 Phacoemulsifier System (K931354) Ocusystem Art Advantage (K991852) OMS Diplomax Phacoemulsifier (K946054)
Intended Use	The Horizon Phacoemulsification System performs phacofragmentation/ phacoemulsification with ultrasonic energy to disrupt and extract cataractous lens material from the eye.
Technological characteristics	The technological characteristics of the Subject Device are the same as the Predicate Devices.
Performance data	Performance data was not required as the Subject Device does not utilize any new technological characteristics or performance specifications than the currently marketed Predicate Devices.

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Device description

The Horizon Phacoemulsification System utilizes the same technology as the currently marketed predicate devices that employ ultrasonic energy to emulsify a cataractous lens and remove it from the eye. The intended use and performance specifications are also comparable to the predicate devices. The subject of this 510(k) is the Horizon Phacoemulsification System's design configuration of a non-invasive vacuum sensing system that maintains sterile fluids, and the unit's software controlled user interface.

The Horizon Phacoemulsification System utilizes an external tubing cartridge venting to the bottle versus air, to minimize the possibility of introducing contamination into the fluid path. The external tubing cartridge design is advantageous as the fluid path is visible to the user, easily removed/ replaced at the end of the case. The Horizon system uses a software-controlled interface that assists the user in not only system set up but in all modes of operation during surgery. The advanced microprocessors allow the surgeon to program surgical parameters for up to six different users by an LCD touch panel display.

The Horizon Phacoemulsification System has similar operation modes as the predicate devices, i.e. Ultrasonic (U/S), Irrigation, Irrigation/ Aspiration (I/A), Vitrectomy, and Diathermy or Coagulation modes utilized in cataract extraction. The component parts of the Horizon Phacoemulsification System include the U/S handpiece, the tubing cartridge, and the footswitch as these items can only be used with this system. The Cautery, Vitrectomy, and Irrigation/ Aspiration devices are universal-type handpieces that are considered additional accessories to the Horizon system.

Conclusion

Based on the 510(k) summaries and the 510(k) statements (21 CFR §807) and the information provided herein, we conclude that the Subject Device is substantially equivalent to the Predicate Devices under the Federal Food, Drug and Cosmetic Act.

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Comparison of device characteristics

The table below lists the characteristics of the Subject Device and Predicate Devices as a comparison of essential components.

Device Characteristics	***Subject Device*** **Horizon Phacoemul-sification System**	***Predicate Device*** **P4000 Phacoemulsifier**	***Predicate Device*** **Ocusystem Art Advantage Phacoemulsifier**	***Predicate Device*** **OMS Diplomax Phacoemulsifier**
Console				
Display	LCD Touch Screen	Touch Pad	Touch Pad	LCD Touch Pad
Pump	Peristaltic, low pulsation	Same	Same	Same
Pump Vacuum Range	0 to 500 mmHg	0 to 500 mmHg	0 to 500 mmHg	0 to 500 mmHg
Aspiration Rate	0 to 50 cc/min	0 to 50 cc/min	0 to 50 cc/min	0 to 44 cc/min
Fluidics	External Fluid Path	External Fluid Path	External Fluid Path	Internal Fluid Path
System Tubing	Reusable Tubing Cartridge*	Disposable/ Reusable Tube Set	Disposable/ Reusable Tubing Set	Disposable/ Reusable T-Fitting
Vent	Fluid Vent	Air Vent	Fluid Vent	Air Vent
Modes	U/S Phaco, Irrigation/ Aspiration, Vitrectomy, Bipolar Coagulation	Same	Same	Same
Programmable User Parameters	Yes	Yes	Yes	Yes
Handpieces				
Material	Titanium	Titanium	Plastic/ Titanium	Stainless Steel/ Titanium
Frequency	40 kHz, 4 crystals	40 kHz, 4 crystals	55 kHz, 4 crystals	38 kHz, 2 crystals
Footswitch				
Operational control	3 mode position, activates reflux	Same	Same	Same

* Disposable tubing is not yet available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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American Optisurgical, Inc.
c/o Nanette Canepa
25501 Arctic Ocean
Lake Forest, CA 92630

Re: K020527
Trade/Device Name: Horizon Phacoemulsification System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: February 15, 2002
Received: February 19, 2002

Dear Ms. Canepa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address. http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K 020527

Device Name: Horizon Phacoemulsification System

Indications for Use: The Horizon Phacoemulsification System performs phacofragmentation/ phacoemulsification with ultrasonic energy to disrupt and extract cataractous lens material from the eye.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

Prescription Use X
(Per 21 CFR 801.109)

510(k) Number K020527

(Optional Format 3-10-98)